DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

January 13, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 16-03

Mr. Elias Perez
San Diego Products, Inc.
1330 La Mirada Drive
San Marcos, CA 92069

Dear Mr. Perez:

The Food and Drug Administration conducted an inspection of your firm located at 1330 La Mirada Drive, San Marcos, CA on September 4 - 6, 2002. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110. At the conclusion of the inspection you were issued a Form FDA-483 (copy enclosed) which delineated a number of gross insanitary conditions present in your facility at the time of that inspection. .We have determined that these conditions cause the products manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) (copy attached) of the Food, Drug, and Cosmetic Act (The Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. You can also find links to the Act at FDA's website at www.fda.gov.

The following is a list of the objectionable conditions observed by our investigator during the inspection.

1. Rodent activity observed on food contact surfaces in the warehouse:

   a) Inside the production room on top of the mechanical room roof directly above the utensil washing and hand washing sinks and the utensil storage area.

b) On the floor along the back wall and all four corners of the warehouse, on top of cases of packaging materials and between the slats of wooden pallets in the warehouse. Rodent pellets, fur and partially consumed nuts were observed on top of the packaging machine stored in the warehouse.

2. Pests observed on the food contact surfaces and in the warehouse:

a) A string of ants was observed moving up the side and around the top rim of a freezer that was used to store dried shrimp and dried nuts. There was a pile of dead ants, too numerous to count, inside the freezer on top of a bag of mixed nuts.

b) Five live spiders were observed inside boxes containing packaged products that were inside the packing room.

c) Dead insects and cobwebs around the recessed ceiling area above the hopper of the packing machine located in the packing room.

d) Spiders and cobwebs observed between boxes of cinnamon and cases of other bulk products and the wall of the warehouse.

e) Flying insects were observed inside the warehouse area. One fly was observed landing on top of a piece of paper that partially covered a plastic tub of dried shrimp.

f) Cobwebs were observed on and around the skylight of the warehouse.

3. Other objectionable conditions and practices include, but are not limited to, the following:

a) Spilled bulk ingredients, including nut pieces and spices were on the floor of the warehouse, under shelves and in the slots of the shelving used to store bulk ingredients.

b) The screen door from the warehouse to the packing room was observed to be left open, often for periods exceeding ½ hour during packing operations. The screen door was observed to be left open on numerous occasions throughout the day.

c) The exterior roll-up loading bay door to the warehouse area of the facility was open from 9:00 AM – 3:30 PM during the inspection. There was no loading activity occurring during the period.

d) There were numerous wooden pallets, furniture, plastic tarps, used cardboard drums and other miscellaneous debris stacked together between the building and the dumpster and between the dumpster and the street along the fence creating potential harborage for rodents or insects.

e) Personal belongings including clothing, miscellaneous items and purses were observed sitting in the production room adjacent to the dish and utensil washing area and the packing machine. Also, personal dishware items were observed to be stored in the same during rack as dishes and utensils used in production.

f) Failure to provide safety-type light bulbs suspended over exposed food, specifically, a tub of dried shrimp that was not fully covered was observed sitting below a fluorescent light fixture that that did not have safety light bulbs or shielding.

g) Use of portable cement mixer, which has metal parts and seams where residue was lodged in crevices, to mix products and spices together. This cement mixer is made of non-stainless steel and has evidence of corrosion and rust.

h) The ceiling inside the warehouse had paneling that was falling off and there was exposed insulation in many areas.

i) Fire extinguisher, tape dispenser, and other miscellaneous items stored on top of food items in a box in the warehouse.

j) Holes in the warehouse walls in numerous locations.

k) There were about 5 rat traps observed in the facility, but only one of the traps was set.

l) Suitable outer garments are not worn that protect against contamination of food contact surfaces.

m) Two female employees failed to wear hair nets and appropriate hair restraints while packing dried shrimp and while performing other production activities.

4. Apparent Discrepancy on the labeling of your product:

Imported mango product has declared Yellow #5 and #6 on original cases. Your product labels for products that incorporated these mangos did not list these colorings.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with the Act. You should take prompt action to correct the violations observed during FDA's most recent inspection. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should describe each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and the date by which each such item will be corrected and documented.

Please direct your written reply to the Attention:
Director, Compliance Branch
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445.

If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer at telephone number 949-798-7628.

Sincerely,

Alonza E. Cruse
District Director

Enclosures:
21 CFR Part 110 and 123.10
Section 402(a) (4) of the FD&C Act